**Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 07 HOSPITALS**

**Chapter 08 Freestanding Medical Facilities**

**Authority: Health-General Article, §2-104 and Subtitle 19-3A, Annotated Code of Maryland**

*10.07.08.01*

**.01 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Accredited hospital" means a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations.

(2) "ACEP" means the American College of Emergency Physicians.

(3) "Affiliated hospital" means a hospital that operates and provides ancillary and support services to the freestanding medical facility.

(4) "Certified medical radiation technologist" means an individual who is certified by the Board of Physicians to practice medical radiation technology in this State.

(5) "Credentialing process" means the process by which a hospital:

(a) Verifies qualifications of a physician;

(b) Delineates clinical privileges of a physician; and

(c) Monitors performance of a physician.

(6) "Department" means the Department of Health and Mental Hygiene.

(7) "Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity including severe pain, psychiatric disturbances, and symptoms of substance abuse such that the absence of immediate medical attention could result in:

(a) Placing the health of the individual in serious jeopardy;

(b) Placing the health of a pregnant woman or unborn child in serious jeopardy;

(c) Serious impairment to any bodily function;

(d) Serious dysfunction of any bodily organ or part; or

(e) With respect to a pregnant woman who is having contractions:

(i) Inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) The transfer posing a threat to the health or safety of the woman or the unborn child.

(8) "Freestanding medical facility" means a facility:

(a) In which medical and health services are provided;

(b) That is physically separated from a hospital or hospital grounds; and

(c) That is an administrative part of a hospital or related institution.

(9) "Hospital" means an institution that:

(a) Has a group of at least five physicians who are organized as a medical staff for the institution;

(b) Maintains facilities to provide, under the supervision of the medical staff, diagnostic and treatment services for two or more unrelated individuals; and

(c) Admits or retains the individuals for overnight care.

(10) "Joint Commission on Accreditation of Healthcare Organizations" means the voluntary national healthcare accreditation service recognized for Medicare certification purposes by Public Law 89-97.

(11) "License" means a document issued by the Secretary to operate a freestanding emergency medical facility in this State.

(12) "Licensed independent practitioner" means any individual permitted by law and by the facility to provide care and services without direction or supervision within the scope of the individual's license and consistent with individually granted clinical privileges.

(13) "Physician" means an individual who is licensed by the Board of Physicians to practice medicine in this State.

(14) "Registered nurse" means an individual who is licensed by the Board of Nursing to practice registered nursing in this State.

(15) "Related institution" means a facility as defined under Health-General Article, §19-301(o), Annotated Code of Maryland.

(16) "Secretary" means the Secretary of Health and Mental Hygiene.

*10.07.08.02*

**.02 Incorporation by Reference.**

A. In this chapter, the following documents are incorporated by reference.

B. Documents Incorporated.

(1) Interhospital Transfer Guidelines Manual; Maryland Institute for Emergency Medical Services Systems, Baltimore, Maryland (January 2002).

(2) ACEP Policy Statement: Emergency Department Planning and Resources Guidelines (June 2004), American College of Emergency Physicians, PO Box 619911, Dallas, Texas 75261-9911.

(3) Guidelines for Design and Construction of Hospital and Healthcare Facilities, 2001 Edition, American Institute of Architects, 1735 New York Avenue, N.W., Washington D.C. 20006, which is incorporated in COMAR 10.07.01.03.

(4) Hospital Accreditation Standards, 2006 Edition, Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Blvd, Oakbrook Terrace, Illinois 60181, which is incorporated in COMAR 10.07.01.09.

(5) U.S. Centers for Disease Control and Prevention Guidelines for Standard Precautions and the federal Occupational Safety and Health Administration/Maryland Occupational Safety and Health, Bloodborne Pathogen Standard 29 CFR §1910.1030 which is incorporated by reference in COMAR 09.12.31.

(6) The Maryland State Fire Prevention Code, which is incorporated by reference in COMAR 29.06.01.

*10.07.08.03*

**.03 Restrictions.**

A freestanding medical facility may not use the name "emergency room", "emergency department", or "hospital" in its title or advertisements or on any signage.

*10.07.08.04*

**.04 Licensure Application Procedure.**

A. A hospital may not establish, operate, or continue to operate an existing freestanding medical facility without first obtaining a license from the Secretary.

B. A hospital desiring to establish a freestanding medical facility shall apply to the Department for initial licensure on a form provided by the Secretary.

C. The application shall state the name of the affiliated accredited hospital.

D. The application shall be accompanied by a nonrefundable 3-year license fee of $3,000.

E. The Secretary shall issue a license to a freestanding medical facility for a term of 3 years if the facility complies with all licensing requirements.

*10.07.08.05*

**.05 Renewal of License.**

A. A licensee shall file an application for license renewal with the Secretary on a form provided by the Secretary.

B. A licensed freestanding medical facility shall apply for licensure within 60 days of the expiration date of its current license.

C. The application for license renewal shall be accompanied by a nonrefundable 3-year license renewal fee of $3,000.

*10.07.08.06*

**.06 Inspections.**

A. A freestanding medical facility shall be open to inspection at all times by the Department for annual licensure surveys, revisit surveys, and complaint investigations.

B. Licensure Standards. When conducting a licensure or complaint survey, the Department shall use this chapter as well as the:

(1) Joint Commission on Accreditation of Healthcare Organization, 2006 Hospital Accreditation Standards;

(2) COMAR 10.07.06;

(3) COMAR 10.07.01.24, .26 and .33; and

(4) ACEP Policy Statement: Emergency Department Planning and Resources Guidelines.

C. Responsibility of the Freestanding Medical Facility. The facility shall make the following documents available for review by the Department:

(1) Policies and procedures;

(2) Minutes of committee meetings; and

(3) Data and documentation related to oversight of the freestanding medical facility at the affiliated hospital.

*10.07.08.07*

**.07 Waiver.**

A. Facilities that are providing services on or before February 12, 2007, but do not meet all requirements of this chapter, may request a waiver of specific requirements from the Department.

B. All other freestanding medical facilities seeking a waiver from this chapter shall submit a request to the Department including the rationale for the waiver and alternatives to the requirement based on clinical and technical advances.

C. In its request, the facility shall demonstrate that a waiver of the requirement would:

(1) Not pose a threat to patients or the provision of services; and

(2) Be a financial hardship for the facility to comply with that requirement.

D. The Department shall review the request for a waiver and notify the freestanding medical facility of its determination.

*10.07.08.08*

**.08 Affiliated Hospitals.**

A. The freestanding medical facility shall be reviewed under the affiliated hospital's accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

B. The governing body of the affiliated hospital shall provide administrative and clinical oversight for the care and services provided by the freestanding medical facility. Services of the facility shall be reviewed and monitored consistent with the hospital's bylaws, including but not limited to:

(1) Patient safety;

(2) Peer review;

(3) Medical staff;

(4) Risk management; and

(5) Quality improvement.

C. The Department may issue a waiver for the requirement for accreditation if the affiliated hospital is not accredited or if the hospital is actively seeking accreditation.

*10.07.08.09*

**.09 Treatment of Patients.**

Regardless of a patient's medical condition, insurance status, or ability to pay, the freestanding medical facility shall provide stabilizing treatment to a patient presenting with an emergency medical condition.

*10.07.08.10*

**.10 Personnel.**

A. Administrative Director. The freestanding medical facility shall have a full-time administrative director who:

(1) Acts as a liaison with the affiliated hospital;

(2) Directs the daily operation of the facility; and

(3) Ensures that employees are capable of providing:

(a) Resuscitation;

(b) Stabilization;

(c) Timely triage; and

(d) Appropriate transfer of all patients; and

(4) Ensures that there is an organized and structured patient safety and quality improvement program to monitor and improve patient care.

B. Medical Director. The facility shall have a Medical Director who is:

(1) A licensed physician; and

(2) Board certified or Board eligible in Emergency Medicine by the:

(a) American College of Emergency Physicians;

(b) American Board of Emergency Medicine; or

(c) American Osteopathic Board of Emergency Medicine.

C. The Medical Director shall provide clinical oversight of the freestanding medical facility.

D. Other Personnel. The freestanding medical facility shall be staffed at all times with a:

(1) Minimum of one physician who is trained in emergency medicine;

(2) Sufficient number of registered nurses and other professionals to provide advanced life support;

(3) Certified medical radiation technologist; and

(4) Laboratory technician.

E. A freestanding medical facility shall be staffed during all hours of operation by licensed independent practitioners, nurses, and ancillary health care professionals with the certification, experience, competencies, and skills necessary for providing basic and advanced life support for children and adults.

F. Credentialing. Physicians and other licensed independent practitioners shall be credentialed consistent with COMAR 10.07.01.24.

G. The facility shall assess its staffing pattern on a regular basis. Staffing patterns shall accommodate the potential for the unexpected arrival of additional patients. The facility shall have a plan for the provision of additional licensed independent practitioners and nurses in times of acute overload.

*10.07.08.11*

**.11 Quality Assurance.**

A. The freestanding medical facility shall develop and implement a quality assurance program.

B. The quality assurance program shall have a quality management process that:

(1) Is multidisciplinary;

(2) Is integrated into the hospital's overall quality management program that is reported to the hospital's governing body;

(3) Has a structure to ensure that defined program outcomes and performance measures are developed and monitored regularly;

(4) Maintains sufficient documentation to:

(a) Verify problems;

(b) Identify opportunities for improvement; and

(c) Show corrective actions taken and resolution of problems;

(5) Includes review of morbidity and mortality; and

(6) Evaluates medical care, nursing care, utilization review, tissue review, and pre-hospital care.

*10.07.08.12*

**.12 Laboratory Services.**

A. The freestanding medical facility shall have on-site laboratory services that are available during the facility's hours of operation.

B. Laboratory Licensure Standards. The facility's laboratory services shall be licensed consistent with:

(1) COMAR 10.10.01;

(2) COMAR 10.10.02;

(3) COMAR 10.10.03;

(4) COMAR 10.10.04;

(5) COMAR 10.10.05;

(6) COMAR 10.10.06;

(7) COMAR 10.10.07; and

(8) COMAR 10.10.08.

C. Laboratory services shall include the "Suggested Laboratory Capabilities", ACEP Policy Statement: Emergency Department Planning and Resources Guidelines, Page 13.

*10.07.08.13*

**.13 Radiology Services.**

A. The freestanding medical facility's radiology services shall comply with all State and federal requirements for licensure.

B. Radiology services shall be available on site at all times that the facility is open for business consistent with "Radiological, Imaging, and Other Diagnostic Services", ACEP Policy Statement: Emergency Department Planning and Resources Guidelines, Page 12, except for the sections related to Nuclear Medicine, Radiographic Services, and Vascular/flow Studies including impedance plethysmography.

*10.07.08.14*

**.14 Pharmacy Services.**

A. Pharmacy services for freestanding medical facility patients may be provided by:

(1) The facility's affiliated hospital; or

(2) A contracted pharmacy.

B. The freestanding medical facility that does not have 24-hour a day, 7-day a week outpatient pharmacy services, shall provide its patients with a list of community pharmacies that offer service 24-hours per day.

C. The facility's pharmacy services shall be provided and operated consistent with all applicable State and federal laws.

D. The freestanding medical facility shall maintain a supply of medications consistent with the "Suggested Pharmacological and Therapeutic Drugs for Emergency Departments", ACEP Policy Statement Emergency Department Planning and Resources Guidelines, Page 11.

E. The facility shall ensure that all drugs and pharmaceuticals are stored securely and maintained within the acceptable level of humidity and temperature.

F. Data and other information about quality oversight of the pharmacy services shall be available to the Department for review and monitoring.

*10.07.08.15*

**.15 Access to Emergency Medical Services.**

An emergency medical facility shall meet the requirements of the Maryland Institute for Emergency Medical Services Systems to be eligible to accept patients through the Emergency Medical System.

*10.07.08.16*

**.16 Transfer of Patients.**

A. The freestanding medical facility shall have pre-arranged transfer agreements with facilities that are capable of providing definitive care appropriate for the nature and severity of the patient's illness or injury.

B. Patient transfers shall be consistent with the Interhospital Transfer Guidelines published by the Maryland Institute for Emergency Medical Services System.

C. When transfer by ambulance is medically necessary the facility shall transfer the patient via:

(1) A hospital owned and operated ambulance service;

(2) A contracted ambulance service; or

(3) An ambulance service through an agreement with the local emergency medical system (EMS) jurisdictional program.

D. The level of care and medical interventions provided by an ambulance during transfer shall be appropriate for the patient's condition.

E. Before transfer, the patient shall:

(1) Be assessed by a physician or licensed independent practitioner; and

(2) Receive stabilizing medical treatment consistent with that of the freestanding medical facility's ability to treat.

F. The freestanding medical facility shall provide the emergency medical system and the receiving facility with the patient's medical records necessary for ongoing care, including:

(1) All treatment provided to the patient;

(2) Medications administered to the patient;

(3) Diagnostic procedures performed for the patient; and

(4) The patient's response to the care at the time of transfer.

*10.07.08.17*

**.17 Medical Records.**

A. The freestanding medical facility shall ensure that staff members develop a legible and appropriate medical record for each patient who visits the facility for treatment.

B. Security and Disclosure of Medical Information. The freestanding medical facility shall:

(1) Maintain records in a secure manner that protects the confidentiality of patient information at all times;

(2) Develop and implement policies and procedures for disclosure of patient medical records and patient access to their medical records, including the costs for retrieving and copying records as defined in Health-General Article, §§4-301— 4-309, Annotated Code of Maryland; and

(3) Make medical records available to emergency medical services agencies for outcome data as directed by the Maryland Institute for Emergency Medical Services System.

C. Retention. The medical record shall be retained as required by all federal and State laws and regulations and shall be made available promptly to the freestanding medical facility staff.

*10.07.08.18*

**.18 Nourishing Snacks.**

A freestanding medical facility shall maintain a supply of nourishing snacks for patients who may require them. The facility shall provide appropriate storage facilities, including refrigeration for the nourishing snacks.

*10.07.08.19*

**.19 Infection Control.**

The freestanding medical facility shall comply with the U.S. Centers for Disease Control and Prevention guidelines for standard precautions and the federal Occupational Safety and Health Administration/Maryland Occupational Safety and Health, Bloodborne Pathogen Standard, except in a life-threatening emergency in which compliance is not feasible or practicable.

*10.07.08.20*

**.20 Equipment and Supplies.**

The freestanding medical facility shall have equipment and supplies available consistent with the "Suggested Equipment and Supplies for Emergency Departments," ACEP Policy Statement: Emergency Department Planning and Resources Guidelines, pages 7—10.

*10.07.08.21*

**.21 Physical Environment.**

A. Construction and Zoning. The freestanding medical facility shall comply with the following construction and zoning requirements:

(1) All federal, State, and local building, construction and zoning laws; and

(2) "Guidelines for Design and Construction of Hospital and Healthcare Facilities, (2001 Edition)," Section 9.6 Freestanding Emergency Facility and other applicable sections.

B. Fire Safety.

(1) The facility shall comply with the Maryland State Fire Prevention Code and applicable local fire prevention codes that are in effect at the time of plans review and construction.

(2) The local fire authority for the proposed facility shall review construction plans and conduct an initial inspection to verify compliance with fire safety requirements before use and occupancy.

(3) An annual fire inspection of the facility is required for license renewal.

C. Housekeeping.

(1) The freestanding medical facility shall be clean and maintained in good repair at all times.

(2) The facility shall employ sufficient staff to provide housekeeping and maintenance services, or the services may be provided under a contractual arrangement.

(3) The facility shall be maintained in a manner that is safe and free of pests or other hazards.

D. Equipment Maintenance.

(1) The freestanding medical facility shall have a preventive maintenance program for all facility systems and equipment.

(2) The facility shall maintain records of preventive maintenance performed and of all service repairs.

(3) Appropriately trained staff employed by the facility or under contractual arrangements shall perform maintenance of clinical equipment.

E. All entrances, including ambulance entrances, shall be clearly marked and accessible at all times.

F. There shall be a sheltered area for off-loading patients from ambulances.

G. The facility shall store and dispose of trash and medical waste consistent with all federal and State laws and regulations.

*10.07.08.22*

**.22 Emergency Preparedness.**

The freestanding medical facility shall develop an emergency preparedness plan to address internal and external emergencies. The emergency plan shall identify the manner by which the facility will interface with local emergency services and the affiliated hospital in the event of a major disaster.

*10.07.08.23*

**.23 Emergency Suspension.**

A. The Secretary may immediately suspend a license on finding that the public health, safety, or welfare imperatively requires emergency action.

B. Notice of Emergency Suspension. The Department shall deliver a written notice to the licensee:

(1) Informing the licensee of the emergency suspension;

(2) Giving the reasons for the action and the regulation or regulations with which the licensee has failed to comply that forms the basis for the emergency suspension; and

(3) Notifying the licensee of its right to request a hearing and to be represented by counsel.

C. The filing of a hearing request does not stay the emergency action.

D. Suspension of License. When a license is suspended by emergency action, the licensee shall:

(1) Immediately return the license to the Department;

(2) Stop providing services immediately; and

(3) Notify patients or the patients' representatives about the suspension and make every reasonable effort to assist them in making other arrangements for services.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing consistent with Regulation .25 this chapter.

F. Show Cause Hearing.

(1) In addition to the right to request a hearing consistent with Regulation .25 of this chapter, a person aggrieved by the action of the Secretary under this regulation shall be given the opportunity for a hearing to show cause why the Department should lift the summary suspension.

(2) The show cause hearing shall be a nonevidentiary hearing to provide the parties with an opportunity for oral argument on the summary suspension.

(3) Show Cause Hearing Procedures. The show cause hearing shall be conducted before the Secretary or a designee of the Secretary, who:

(a) Shall determine procedural issues;

(b) May impose reasonable time limits on each party's oral argument; and

(c) Shall make rulings reasonably necessary to facilitate the effective and efficient operation of the show cause hearing.

(4) Results of a Show Cause Hearing. At the conclusion of the show cause hearing, the Secretary or the Secretary's designee may:

(a) Affirm the order of summary suspension;

(b) Rescind the order of summary suspension;

(c) Enter into a consent order; or

(d) Enter into an interim order warranted by the circumstances of the case, including one providing for a stay of the summary suspension subject to certain conditions.

(5) After the show cause hearing, if the Secretary or the Secretary's designee decides to continue the summary suspension, the person aggrieved by the decision may request an evidentiary hearing before the Office of Administrative Hearings consistent with Regulation .25 of this chapter.

*10.07.08.24*

**.24 Sanctions.**

A. In addition to other penalties available under State law, the Department may impose sanctions against a freestanding medical facility that fails to comply with Health-General Article, Subtitle 3A, Annotated Code of Maryland, or the regulations of this chapter. The sanctions include:

(1) A civil penalty not to exceed $10,000;

(2) Restrictions on the operation of the freestanding medical facility;

(3) A directed plan of correction; and

(4) Suspension or revocation of the freestanding medical facility's license.

B. Except as otherwise provided under the Administrative Procedure Act, State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland, before the Department may impose any sanctions under §A of this regulation, the Department shall provide the freestanding medical facility notice and an opportunity for a hearing and judicial review under the Administrative Procedure Act.

C. Before the Department imposes a directed plan of correction, the Department shall give the freestanding medical facility notice and the opportunity for a prompt informal hearing with the Director of the Office of Health Care Quality.

*10.07.08.25*

**.25 Hearings.**

A. The licensee shall file a request for a hearing with the Office of Administrative Hearings, with a copy to the Office of Health Care Quality of the Department, not later than 30 days after receipt of notice of the Secretary's action. The request shall include a copy of the Secretary's action.

B. A hearing requested under this chapter shall be conducted consistent with State Government Article, §10-201 et seq., Annotated Code of Maryland, and COMAR 28.02.01 and 10.01.03.

C. The burden of proof is as set forth in COMAR 10.01.03.28.

D. Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in COMAR 28.02.01.

E. The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35.

F. The Secretary shall issue a final decision consistent with COMAR 10.01.03.35.